In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-750V Filed: November 21, 2017 Not to be Published.

<u>Anthony F. Chapekis</u>, Chicago, IL, for petitioner. <u>Ann D. Martin</u>, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

On August 19, 2014, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that human papillomavirus ("HPV" or "Gardasil") vaccine administered August 25, 2011 caused an intense skin reaction to her sweat, chlorine, and soap among other substances; hyperactivity, anxiety; skin rashes; and permanent disfigurement. Pet. Preamble and ¶¶ 4-7. Petitioner did not file medical records until November 26, 2014, three months after she filed the petition. Petitioner did not file her affidavit until July 24, 2015, eleven months after she filed her petition. She did not file additional medical records until July 29, 2015. Even then, petitioner had more medical records which she never filed.

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall redact such material from public access.

On September 24, 2015, respondent filed his Rule 4(c) Report opposing compensation.

On October 14, 2015, the undersigned issued an Order setting a deadline of July 13, 2016 (one year later) for petitioner to file an expert report. The reason the undersigned gave petitioner one year to file an expert report is that the pattern of petitioner's behavior was to delay constantly and not respond appropriately to orders. Petitioner did not file an expert report by the deadline one year later or ever.

A year after the expert report was due, on July 7, 2017, petitioner moved for discovery from Merck, the manufacturer of Gardasil, of samples of the prior (2011) formula of Gardasil vaccine; chemical and clinical facts/notes regarding the former formulation of Gardasil and subsequent formulas; information regarding the changes in the formula and the reasons for the changes; and any further information to enable a clinician to form an opinion "theoretically linking the injuries" petitioner claimed the vaccine caused. Pet. Mot. at ¶ 13.

On July 10, 2017, the undersigned denied petitioner's motion for discovery. Most of petitioner's medical records refer to her having acne vulgaris, not urticarial (hives) and rashes. Order at 5. The undersigned regarded petitioner's motion for discovery consistent with the pattern of petitioner's numerous efforts to delay resolution of the case. Id. at 6.

On July 13, 2017, after a telephonic status conference in which petitioner's counsel stated that petitioner was less than responsive, the undersigned issued an Order stating that if petitioner did not file medical records from her current doctor, Dr. Ioannis Moissidis, by November 17, 2017, the undersigned would dismiss this case for failure to prosecute under Vaccine Rule 21(b)(1).

Petitioner did not file anything by November 17, 2017. The undersigned now **DISMISSES** this case for failure to prosecute.

FACTS

Pre-Vaccination Records

On March 2, 2009, petitioner saw Dr. Patricia Stec, complaining of a runny nose, stuffy nose, coughing, headache, dizziness for 10 days, and anxiety. Med. recs. Ex. 3, at 24.

On July 5, 2010, petitioner saw her doctor because she noticed she was unable fully to extend her arms past 170 degrees bilaterally in cheerleading. <u>Id.</u> She received her first Gardasil vaccination. <u>Id.</u>

On October 16, 2010, petitioner returned to her doctor for her second Gardasil vaccination. <u>Id.</u> She said she felt dizzy after her last vaccination but recovered quickly and felt good afterwards.

Post-Vaccination Records

On August 25, 2011, petitioner received her third Gardasil vaccination. Med. recs. Ex. 3, at 20.

On August 26, 2011, petitioner telephoned Dr. Frank Roemisch and said she had transient urticaria (hives) the prior night, which was eight hours after Gardasil and when petitioner was very stressed regarding time constraints to do her homework. Med. recs. Ex. 5, at 36. Petitioner's urticaria was resolved with Benadryl taken the prior night and repeated that morning. She did not have systemic symptoms. <u>Id.</u>

On August 27, 2011, petitioner telephoned Dr. Roemisch and said her hives relapsed without systemic symptoms. <u>Id.</u> Dr. Roemisch said to take a cool shower and use Benadryl. She was to call on August 29, 2011 or as needed if she had any new or increased symptoms. She was to start a trigger diary. <u>Id.</u>

On October 8, 2011, petitioner saw Dr. Roemisch, complaining of a body rash and severe pruritis (itching) since August 26, 2011, especially on her upper body and arms. Med. recs. Ex. 3, at 25. Benadryl helped, but made her drowsy. She had an increase in pruritis after a gym class. <u>Id.</u> On a physical examination, petitioner had generalized urticaria with some minor excoriations. Med. recs. Ex. 5, at 37. Dr. Roemisch prescribed Prednisone 20 mg. If petitioner's symptoms increased or persisted, she was to use Xyzal² 5 mg. and see an allergist. <u>Id.</u>

On October 15, 2011, petitioner telephoned Dr. Roemisch and said her pruritis decreased, she was off Prednisone, and she did not use Xyzal. <u>Id.</u>

On November 1, 2011, petitioner saw LPN Reyna Garcia, who works with Dr. Stec. <u>Id.</u> at 33. Petitioner thought she might have scratched her eye. On examination, petitioner was noted to have moderate inflammatory acne on her face for which LPN Garcia prescribed Atralin 0.05% gel. <u>Id.</u>

On April 19, 2012, petitioner telephoned Dr. Roemisch, complaining of pruritus and rashes with multiple lotions and exercise. <u>Id.</u> at 37. She told Dr. Roemisch that Xyzal was too strong. Benadryl was effective but did not last six hours. Petitioner had not seen an allergist because she had not found a Greek allergist and did not have insurance. Dr. Roemisch prescribed Claritin 5 mg. If that did not work, she should try Singulair, and if that failed, she should consider adding a H₂ blocker. He said not to use the gym for two months. <u>Id.</u>

On April 17, 2013, petitioner saw Dr. Vassilios Dimitropoulos, a dermatologist, who

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² Xyzal is "trademark for a preparation of levocetirizine dihydrochloride." <u>Dorland's Illustrated Medical Dictionary</u> 2088 (32nd ed. 2012) (hereinafter, "Dorland's"). Levocetirizine dihydrochloride is "a histamine H₁-receptor antagonist used in treatment of allergic rhinitis and chronic idiopathic urticaria...." Dorland's at 1032.

diagnosed her with acne vulgaris on her face, chest, and back, post-inflammatory hyperpigmentation, and xerosis (abnormally dry skin). Med. recs. Ex. 2, at 14. Petitioner had had acne for six years. <u>Id.</u> (This would put onset of her acne in 2007, four years before her third HPV vaccination.) On a physical examination, petitioner had numerous erythematous papules, rare pustules, multiple excoriations, and numerous open and closed comedones.³ <u>Id.</u> at 15. She had many erythematous inflammatory stains. <u>Id.</u> Dr. Dimitropoulos prescribed Minocycline⁴ 100mg and Tretinoin⁵ 0.025% cream. <u>Id.</u> at 16.

On June 19, 2013, petitioner returned to Dr. Dimitropoulos. <u>Id.</u> at 10. Her acne was not itching, painful, or burning. It was localized to her face. <u>Id.</u>

On August 14, 2013, petitioner returned to Dr. Dimitropoulos. <u>Id.</u> at 1. He diagnosed her with improving acne vulgaris and post-inflammatory hyperpigmentation. <u>Id.</u> at 5. Petitioner had an allergic reaction to Cefuroxime⁶ in the form of a rash. <u>Id.</u> at 2.

On February 5, 2014, petitioner returned to Dr. Dimitropoulos. <u>Id.</u> at 6. Her acne was mild, localized to her face, and characterized by blackheads. It did not itch, and was not painful or burning. <u>Id.</u>

On January 7, 2015, petitioner returned to Dr. Dimitropoulos. Med. recs. Ex. 4, at 27. She had facial acne, dermatographism⁷ on her arms, post-inflammatory hyperpigmentation, photodamage, and lentigos.⁸ <u>Id.</u> Dr. Dimitropoulos discussed petitioner seeing an immunologist and allergist. <u>Id.</u>

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion

³ Comedones are the plural of "comedo." A comedo is a "noninflammatory lesion of acne vulgaris and a few other conditions, consisting of a plug of keratin and sebum within the dilated orifice of a hair follicle; it usually contains bacteria" <u>Dorland's</u> at 390.

⁴ Minocycline is "a semisynthetic broad-spectrum antibiotic of the tetracycline group." <u>Dorland's</u> at 1168.

⁵ Tretinoin is "all-*trans*-retinoic acid, applied topically in the treatment of acne vulgaris" <u>Dorland's</u> at 1959.

⁶ Cefuroxime is "a synthetic, broad-spectrum β-lactase-resistant, second-generation cephalosporin effective against a wide range of gram-positive and gram-negative bacteria." <u>Dorland's</u> at 312.

⁷ Dermatographism also known as dermographism is "a type of physical urticaria in which moderately firm stroking or scratching of the skin with a dull instrument produces a wheal with a red flare on each side." <u>Dorland's</u> at 499.

⁸ Lentigo is "a small, flat, tan to dark brown or black, macular melanosis on the skin; it resembles a freckle clinically but is histologically distinct" <u>Dorland's</u> at 1022.

in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause of and effect showing that the vaccination was the reason for the injury [,]" the logical sequence being supported by a "reputable medical or scientific explanation[,]" <u>i.e.</u>, "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." <u>Grant</u>, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for Gardasil vaccine, she would not have had rashes and other alleged injuries, but also that Gardasil vaccine was a substantial factor in causing her rashes and other alleged injuries. <u>Shyface v. Sec'y of HHS</u>, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Vaccine Act, 42 U.S.C. § 300aa-13(a)(1), prohibits the undersigned from ruling for petitioner based solely on her allegations unsubstantiated by medical records or medical opinion. The medical records do not support petitioner's allegations. She has not filed a medical expert opinion in support of her allegations.

The undersigned **DISMISSES** this petition for failure to prosecute under Vaccine Rule 21(b)(1).

CONCLUSION

The petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment herewith.⁹

IT IS SO ORDERED.

Dated: November 21, 2017

/s/ Laura D. Millman Laura D. Millman Special Master

⁹ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.